



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/598,890	06/22/2000	Manfred Berndt	4481-022	8565

7590 07/23/2002

Lowe Hauptman Gopstein Gilman & Berner LLP
1700 Diagonal Road Suite 310
Alexandria, VA 22314

EXAMINER

GORDON, BRIAN R

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/598,890

Applicant(s)

BERNDT, MANFRED

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3" has been used to designate both microchip and supply. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "6" has been used to designate sensors and detected, OK detection point, and detection. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
4. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. From the description of Figure 1, the examiner assumes that it is prior art. If the assumption is correct then the drawing should be corrected as stated above.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "70" has been used to designate hollow channels or tubes and hollow paths and supply lines. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. The terms of the elements should be consistent.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "53" has been used to designate both recesses and counter electrodes. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "56" has been used to designate both supply device and cartridge. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "8" has been used to designate both signals and signal-processing device. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. ok

The reference numerals in Figure 1 are used to label different operational steps however the steps are not clearly and consistently labeled throughout the discloser.

The same numerals that represent the method steps of the flow diagram are also used to designate structural elements of the device. O/C

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use. OK

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

There are no section headings in the specification.

9. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a **single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

OK

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

OK

The "(Fig. 4a)" on the page of the Abstract should be deleted.

10. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

OK

11. The claims are objected to because the lines are crowded too closely together, making reading and entry of amendments difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

OK

12. The disclosure is objected to because of the following informalities:

The specification contains numerous British spellings of words the English spellings are preferable.

OK

On page 4, line 38 the word remained should be remain.

OK

On page 9, lines 14-18 is a run-on sentence that appears to be missing a verb before the word "to" in line 14. *See pg 16 line 6*

On page 9, line 14 – page 10 line 30 describes Figures 4a and 4b. The examiner recognizes that figure 4a shows two different embodiments of the supply element; however, applicant attempts to describe both embodiments simultaneously in the specification. As a result, it is unclear what elements are contained in each embodiment. For example the element 70 is labeled once in the embodiment on the left, but it is not labeled in the figure on the right therefore it is unclear to the examiner which element in the embodiment on the right is 70. The examiner suggests that applicant separate the two figures into two figures and provide a separate description for each in order to provide a clear description of both embodiments of the invention. Applicant also uses the term "interface element" rather than "supply element" to describe the invention for the purpose of clarity the examiner suggests that applicant be consistent with use of terminology used to describe the invention.

Appropriate correction is required.

13. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant fails to specifically refer to the elements the invention as the terminology (first supplier, second supplier, third supplier, and fourth supplier) used in the claims; therefore it is unclear exactly which elements of the invention are considered to be the first supplier, second supplier, third supplier, and fourth supplier.

Art Unit: 1743

The specification recites that the device comprises a seal; however, it is not recited that the seal is opened by a first supplier in response to the supply element when the microchip and supply element are brought together.

OK pg 4
lines 20-24
of original spec

The specification also fails to recite that the seal is a chemically resistant substance.

The specification also fails to recite that the device comprises an encapsulation.

The specification does not recite that the membrane is formed from a chemically resistant material.

OK

As to claims 9-11, the specification does not describe substances A, B, or C as being samples or reagents.

There is no support for the term operating device used in claims 13 and 16.

most
claims
canceled

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear how the device would be used or operated. It is understood that the tubes or supply element is sealed via a membrane or wax sealant; however, it is unclear how the seal and membrane is pierced/opened to allow the substance to flow to the microchip. Upon piercing it would seem as though the wax

or membrane material that is pierced would also flow to the microchip which would interfere with the analysis or flow of the substances through the channels. The specification does not specifically recite what happens to the sealing material or how it is opened.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1-2, 4, 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear exactly which elements of the invention are considered to be the first supplier, second supplier, third supplier, and fourth supplier.

Claim 1 recites, "opening the third supplier at least to the microchip in response"; it appears as if the phrase is incomplete. In response to what?

Claim 2 appears to be a run-on sentence. It is unclear what is meant by the phrase "for opening the seal in response to the supply element and microchip are brought together".

It is unclear what applicant intends to be an encapsulation. The terms encapsulation and seal could be interpreted to have the same meaning, therefore claims 2 and 4 would be considered duplicates of each other.

As to claims 13 and 16, it is unclear how the supply element, supply equipment, microchip, and operating device are structurally related and operate together.

Art Unit: 1743

18. Claim 1 recites the limitation "for supplying **the substances**" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Braun, Sr. et al., Hubbard et al., Kazumichi et al., Chow (2002/0015667; ,089), Parce et al., Cherukuri et al., Chow et al. (,787; ,089), Dubrow et al. (,175; ,343), Wohlstadter et al., Kennedy (,498 and ,740), Demers et al., Kambara et al., Karger et al., Southgate et al., Ramsey, and Natelson disclose sample holding, transfer, and analysis devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7719 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Application/Control Number: 09/598,890

Page 10

Art Unit: 1743

brg

July 16, 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700